DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K093579
Prostate Mechanical Imager (PMI)
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 876.2050
Regulation Name: Prostate Lesion Documentation System
Regulatory Classification: Class II
Product Code: OQT
Dated: May 21, 2010
Received: May 21, 2010

Dear Dr. Sarvazyan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the Prostate Mechanical Imager (PMI), a prescription device under 21 CFR Part 801.109 that is indicated for the production of an elasticity image of the prostate as an aid in documenting prostate abnormalities that were previously identified by digital rectal examination (DRE). The device utilizes a transrectal probe with pressure sensor arrays and a motion tracking system and provides real-time elasticity images of the prostate. This device is limited to use as a documentation tool and therefore is not to be used for cancer diagnosis or for any other diagnostic purpose. This device is only to be used to image and document an abnormality that was already identified by DRE. Clinical management decisions are not to be made on the basis of information from the PMI device, but rather on the basis of the DRE. If there is disagreement between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., prostate-specific antigen (PSA) levels) in accordance with standard medical practice. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Prostate Mechanical Imager (PMI), and substantially equivalent devices of this generic type, into class II under the generic name, Prostate Lesion Documentation System.

FDA identifies this generic type of device as:

> Prostate Lesion Documentation System -- a device intended for use in producing an image of the prostate as an aid in documenting prostate abnormalities previously identified during a digital

rectal examination. The device uses pressure sensors and image reconstruction software to produce a prostate image that highlights regional differences in intraprostatic tissue elasticity or stiffness. The device is limited to use as a documentation tool and is not intended for diagnostic purposes or for influencing any clinical decisions.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 22, 2010, automatically classifying the Prostate Mechanical Imager in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On May 21, 2010, FDA filed your petition requesting classification of the Prostate Mechanical Imager into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Prostate Mechanical Imager into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the Prostate Mechanical Imager is indicated for:

the production of an elasticity image of the prostate as an aid in documenting prostate abnormalities that were previously identified by digital rectal examination (DRE). The device utilizes a transrectal probe with pressure sensor arrays and a motion tracking system and provides real-time elasticity images of the prostate. This device is limited to use as a documentation tool and therefore is not to be used for cancer diagnosis or for any other diagnostic purpose. This device is only to be used to image and document an abnormality that was already identified by DRE. Clinical management decisions are not to be made on the basis of information from the PMI

device, but rather on the basis of the DRE. If there is disagreement between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., prostate-specific antigen (PSA) levels) in accordance with standard medical practice.

This device can be classified in class II with the establishment of special controls and FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type. The potential risks and mitigations associated with the device type are summarized in Table 1.

Table 1. Potential Risks and Mitigations

Identified Risk	Mitigation Measures
Failure to consistently produce an accurate image	Performance Testing (non-clinical and clinical) Software Verification, Validation, and Hazard Analysis Labeling
Misinterpretation of displayed images	Labeling
User error	Labeling
Microbial contamination from reusable components	Labeling Validation of Reprocessing Methods and Instructions
Adverse tissue reaction	Biocompatibility Testing
Electromagnetic incompatibility	Electromagnetic Compatibility Testing
Electrical injury	Electrical Safety Testing
Thermal injury	Thermal Safety Testing
Mechanical injury	Mechanical Safety Testing

In addition to the general controls of the FD&C Act, the Prostate Lesion Documentation System is subject to the following special controls: (1) The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109; (2) The labeling must include specific information needed to ensure proper use of the device and instructions needed to ensure safe and effective use of the device; (3) Appropriate analysis/testing should validate electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety; (4) Non-clinical and clinical performance testing should demonstrate the accuracy and reproducibility of the constructed image; (5) Appropriate software verification, validation, and hazard analysis should be performed; (6)

All elements of the device that may contact the patient should be demonstrated to be biocompatible; and (7) Methods and instructions for reprocessing of any reusable components should be properly validated.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, this device type is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Prostate Lesion Documentation System they intend to market and receive clearance to market from FDA prior to marketing the device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mr. Robert De Luca at (301) 796-6551.

Sincerely yours,

Jonette Foy, Ph.D.
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health